

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

CARRIE SMITH, Individually and On Behalf of All Others Similarly Situated,	)	
	)	
Plaintiff,	)	<b>CIVIL ACTION NO. 08-cv-00021</b>
	)	
vs.	)	
	)	
SANOFI-AVENTIS, JEAN-FRANCOIS DEHECQ, GERARD LE FUR, HANSPETER SPEK, MARC CLUZEL and JEAN-PIERRE LEHNER,	)	CLASS ACTION COMPLAINT
	)	
Defendants.	)	<b><u>JURY TRIAL DEMANDED</u></b>
	)	
	)	
	)	

Plaintiff, Carrie Smith ("Plaintiff"), alleges the following based upon the investigation by Plaintiff's counsel, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Sanofi-Aventis ("Sanofi" or the "Company"), securities analysts' reports and advisories about the Company, and information readily available on the Internet, and Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a federal class action on behalf of purchasers of Sanofi's securities between February 17, 2006 and June 13, 2007, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the Exchange Act).

2. Sanofi is a pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. The Company's business includes two main activities: pharmaceuticals and human vaccines. In its pharmaceutical activity, the Company specializes in six therapeutic areas: thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system and internal medicine. In the human vaccines activity, the Company offers vaccines in five areas: pediatric combination vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines and travel vaccines.

3. On June 13, 2007, an Advisory Panel to the Food and Drug Administration ("FDA") unanimously voted that Sanofi had not provided the panel with enough information on the safety of Zimulti (rimonabant), and unanimously recommended that the FDA reject Sanofi's Zimulti application. FDA scientists provided an analysis of 13 studies which showed that 26 percent of patients taking the recommended dose of Zimulti had psychiatric side effects, as compared to 14 percent of those patients who received a placebo. Additionally, studies showed that the drug also doubled cases of anxiety, depression, and other mood disorders when compared to placebo. Analysts had predicted that Zimulti would have been a multibillion-dollar product worldwide, assuming that it was approved in the US, which would have been the biggest market for the drug.

4. On this news, the Company's securities declined \$1.31 per share, or 2.95 percent, to close on June 13, 2007 at \$43.07 per share, on unusually heavy trading volume. The following day, the Company's securities declined an additional \$1.74 per share, or over 4 percent, also on unusually heavy trading volume, for a two-day decline of \$3.05 per share, or over 6.87 percent.

5. The Complaint alleges that, throughout the Class Period, defendants failed to

disclose material adverse data concerning Zimulti's tendency to cause a statistically significant increase in psychiatric problems, including suicidal thoughts and actions.

6. As a result of defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class Members have suffered significant losses and damages.

### **JURISDICTION AND VENUE**

7. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

9. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this Judicial District. Additionally, the Company's securities are actively traded on the New York Stock Exchange ("NYSE").

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **PARTIES**

11. Plaintiff, Carrie Smith, as set forth in the accompanying certification, incorporated by reference herein, purchased Sanofi's securities at artificially inflated prices during the Class

Period and has been damaged thereby.

12. Defendant Sanofi is a French corporation with its principal executive offices located at 174 Avenue de France, Paris, France.

13. Defendant Jean-Francois Dehecq ("Dehecq") was, at relevant times, the Company's Chief Executive Officer ("CEO") and Chairman of the Board of Directors.

14. Defendant Gerard Le Fur ("Le Fur") was, at relevant times, the Company's CEO.

15. Defendant Hanspeter Spek ("Spek") was, at all relevant times, the Company's Executive Vice President of Pharmaceutical Operations.

16. Defendant Marc Cluzel ("Cluzel") was, at all relevant times, the Company's Senior Vice President of Scientific and Medial Affairs.

17. Defendant Jean-Pierre Lehner ("Lehner") was, at all relevant times, the Company's Senior Vice President of Medical and Regulatory Affairs

18. Defendants Dehecq, Le Fur, Spek, Cluzel and Lehner are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Sanofi's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. Each defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and misleading. The

Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

19. Sanofi is a pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. The Company's business includes two main activities: pharmaceuticals and human vaccines. In its pharmaceutical activity, the Company specializes in six therapeutic areas: thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system and internal medicine. In the human vaccines activity, the Company offers vaccines in five areas: pediatric combination vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines and travel vaccines.

### **Materially False and Misleading Statements Issued During the Class Period**

20. The Class Period begins on February 17, 2006. On this day, the Company issued a press release entitled "Sanofi-aventis received from the FDA an approvable letter for rimonabant for weight management and a non approvable letter for smoking cessation." Therein, the Company, in relevant part, stated:

Sanofi-aventis announced today that it has received from the U.S. Food and Drug Administration (FDA), Division of Metabolism and Endocrinology Products an approvable letter for rimonabant for weight management, and from the Division of Anesthesia, Analgesia and Rheumatology Products a non approvable letter for smoking cessation.

Sanofi-aventis will continue to work in close collaboration with the FDA.

21. On October 27, 2006, the Company issued a press release entitled "The Lancet

Publishes RIO-DiabetesSstudy; Study Shows Rimonabant Significantly Improves Weight, Blood Sugar Levels and Other Cardiometabolic Risk Factors in People with Type 2 Diabetes."

Therein, the Company, in relevant part, stated:

Sanofi-aventis announced today that the results of the RIO-Diabetes trial were posted on *The Lancet* online edition (publication in the print edition is expected shortly). ***The one-year trial showed that rimonabant 20 mg once daily significantly improved several cardiometabolic risk factors including weight, HbA1c (a measure of blood sugar control), HDL-cholesterol (good cholesterol) and triglycerides (fats in the blood), systolic blood pressure as well as waist circumference (a marker of intra-abdominal adiposity) in overweight / obese patients with type 2 diabetes*** uncontrolled with metformin or sulfonylurea. Importantly, over 50% of the improvements in HbA1c and HDL-cholesterol were independent of the weight loss achieved, suggesting a direct effect of rimonabant on these parameters.

\* \* \*

The RIO-Diabetes study also assessed the safety and tolerability of rimonabant 20 mg once daily, 5 mg once daily and placebo, the results of which were consistent with the data from the entire RIO clinical trial programme which involved more than 6,600 patients. ***Side effects were mainly mild, transient, self-limiting and occurred early in the treatment period. The most frequent side effects included nausea*** (12.1% for rimonabant 20 mg once daily vs. 5.7% for placebo), ***dizziness*** (9.1% for rimonabant 20 mg once daily vs. 4.9% for placebo), ***diarrhoea*** (7.4% for rimonabant 20 mg once daily vs. 6.6% for placebo), ***vomiting*** (5.9% for rimonabant 20 mg once daily vs. 2.3% for placebo), ***self-reported hypoglycaemia*** (5.3% for rimonabant 20 mg once daily vs. 1.7% for placebo), ***fatigue*** (5.3% for rimonabant 20 mg once daily vs. 3.7% for placebo) ***and anxiety*** (5.0% for rimonabant 20 mg once daily vs. 2.6% for placebo). Discontinuation rates due to adverse events were consistent with those reported in other trials in the RIO programme (15% for rimonabant 20 mg once daily vs. 5% for placebo,  $p < 0.005$ ). ***The most frequent adverse events leading to discontinuation were depressed mood disorders, nausea and dizziness.***

Sanofi-aventis received an approvable letter for rimonabant from the U.S. Food and Drug Administration (FDA) in February, 2006. In Europe, rimonabant, known as ACOMPLIA® is approved as an adjunct to diet and exercise for the treatment of obese patients

(BMI  $\geq$  30kg/m<sup>2</sup>), or overweight patients (BMI>27kg/m<sup>2</sup>) with associated risk factors, such as type 2 diabetes or dyslipidemia. [Emphasis added. Internal references omitted.]

22. On December 5, 2006, the Company issued a press release entitled "New Data Shows ACOMPLIA® (rimonabant) Benefited Patients with Type 2 Diabetes by Improving Blood Sugar Control, Reducing Weight and Acting on Other Cardiometabolic Risk Factors; First Rimonabant Trial with HbA1c as a Primary Endpoint." Therein, the Company, in relevant part, stated:

Sanofi-aventis announced today that new data on rimonabant, its first-in-class cannabinoid type 1 (CB1) receptor blocker, *showed that patients with type 2 diabetes not currently treated with anti-diabetic medications experienced significant improvements in blood sugar control and weight as well as other risk factors such as HDL-cholesterol (good cholesterol) and triglycerides when compared to placebo.* The study, called SERENADE, was presented today at the International Diabetes Federation (IDF) World Diabetes Congress in Cape Town, South Africa. *SERENADE is the second study demonstrating that rimonabant significantly improved blood sugar levels in people with type 2 diabetes.*

\* \* \*

*The most common side effects with placebo and rimonabant 20 mg reported in the SERENADE trial were dizziness (2.1% vs. 10.9%), nausea (3.6% vs. 8.7%), nasopharyngitis (7.9% vs. 7.2%), upper respiratory tract infection (2.7 % vs. 7.2%), anxiety (3.6% vs. 5.8%), depressed mood (0.7% vs. 5.8%), and headache (6.4% vs. 3.6%).* The rate of serious adverse events was 3.6% for patients in the placebo arm versus 6.5% for patients in the rimonabant 20 mg.

Overall, discontinuation rates due to adverse events in the trial were 2.1% in placebo-treated patients versus 9.4% for patients on rimonabant 20 mg. *The most common adverse events leading to discontinuation for the placebo and rimonabant 20 mg patients, respectively, were nausea (0% vs. 2.2%), depressed mood disorder (0% vs. 2.2%) and paraesthesia (0% vs. 2.2%).* [Emphasis added. Internal references omitted.]

23. On December 8, 2006, the Company issued a press release entitled "Rimonabant

Update in the United States." Therein, the Company, in relevant part, stated:

Sanofi-aventis announces that concerning the new drug application for rimonabant in the United States, the Food and Drug Administration has considered its October 26, 2006 resubmission to be a complete, class 2 response to the FDA February 17, 2006 action letter.

24. On February 12, 2007, the Company issued a press release entitled "Rimonabant USA: Update." Therein, the Company, in relevant part, stated:

Sanofi-aventis announced today that the review period of rimonabant in the United States has been extended by three months, until July 27, 2007.

The Group also announced the submission of the SERENADE clinical study report today in the rimonabant NDA submitted to the FDA.

25. On March 26, 2007, the Company issued another press release entitled "Rimonabant USA: Update." Therein, the Company, in relevant part, stated:

Sanofi-aventis acknowledges FDA announcement of an Advisory Committee Meeting for rimonabant

Sanofi-aventis announced today the FDA notice for its first in class CB1 receptor antagonist rimonabant, now scheduled for an Endocrinologic and Metabolic Drugs Advisory Committee Meeting to be held on June 13, 2007.

***The Committee will discuss the efficacy and safety of rimonabant in obesity.***

***Sanofi-aventis is pleased to have the opportunity to present its data on rimonabant and to exchange with experts.*** [Emphasis added.]

26. In support of its Zimulti application, and in preparation for the FDA Advisory Committee's meeting, on May 10, 2007, Sanofi submitted its "Briefing Information" to the FDA which included updated clinical trial data.

27. The statements contained in ¶¶ 20 – 26 were materially false and misleading when



made because defendants failed to disclose material adverse data concerning Zimulti's tendency to cause a statistically significant increase in psychiatric problems, including suicidal thoughts and actions.

### **The Truth Begins to Emerge**

28. On June 13, 2007, the FDA's Advisory Panel unanimously voted that Sanfi had not provided the panel with enough information on the safety of Zimulti, and unanimously recommended that the FDA reject Sanofi's Zimulti application. As *WebMD.com* reported:

#### **FDA Panel Rejects Obesity Drug Zimulti**

#### **Experts Concerned About Possible Risks of Suicidal Thoughts in Drug Formerly Called Acomplia**

A new weight loss drug designed for obese adults failed to win approval from an FDA advisory panel Wednesday, *mainly because of fears that it can lead to depression and suicidal thoughts in some patients.*

Outside experts unanimously rejected the bid of Sanofi-Aventis to market Zimulti (rimonabant) in the U.S. despite its approval in dozens of other countries. The drug was previously known as Acomplia.

*"My level of concern ... is very high," says Sid Gilman, MD, a member of the panel and a professor of neurology at the University of Michigan.*

*"I think this is a drug that needs further understanding with respect to what it does to people's psyche," he says.*

*The panel's conclusion, in a 14-0 vote, throws up a major hurdle in a longtime effort by its manufacturer to market the drug in the U.S. The decision makes it unlikely that regulators will approve the drug for U.S. sales because the FDA usually follows the recommendations of its advisory panels.*

Studies conducted by its manufacturer, Sanofi-Aventis, show that many obese patients can lose up to 10% of their body weight after one year on the drug. It also appears to improve blood sugar control in obese diabetes patients.

#### **Regulatory Battle**

In early 2006, the FDA was close to approving the drug, which at the time carried the brand name Acomplia.

But the agency asked the company first to study reports that the drug seemed to cause depression and suicidal thoughts and behaviors in some patients. It also asked Sanofi-Aventis to abandon the name Acomplia because regulators considered it potentially misleading to consumers.

The company responded by offering to minimize the risk by urging doctors not to use the drug in patients with a history of depression or other mental illnesses. In the process, the name Acomplia was changed to Zimulti.

### **Psychiatric Risk**

Company officials clashed with regulators over the size of the psychiatric risk, saying that thousand of patients who took the drug had suicide rates essentially identical to the general population. *Sanofi-Aventis said they'd found a 30% increase in the risk of suicidal thoughts with the drug but that in studies those thoughts almost never led to suicide attempts.*

"The safety profile can only be interpreted in light of the demonstrated benefits," Paul Chew, MD, Sanofi-Aventis' vice president for international clinical development, told the committee.

*But FDA scientists countered with an analysis of 13 studies showing that the drug nearly doubled suicidal thinking while also doubling cases of anxiety, depression, and other mood disorders.*

*Amy Egan, MD, an FDA safety official, says the agency had become worried because the company excluded patients being treated for depression from its analysis.* [Emphasis added.]

29. Also on June 13, 2007, *TheStreet.com* published an article entitled "Serious Setback for Sanofi," which in relevant part stated:

Medical advisers to the Food and Drug Administration said Wednesday that the agency should reject a weight-loss drug from Sanofi-Aventis (SNY) because the medication's risks appear to be greater than its benefits.

*The panel first voted 14-0 that the company hadn't provided enough information on the safety of the drug called Zimulti.*

*Then, the experts unanimously recommended that the FDA reject it.*

*The FDA isn't bound by its advisers' recommendations, but it usually follows them. The FDA is scheduled to make a formal ruling in late July.*

*For Sanofi-Aventis, the panel's decision is a major blow. The drug, under the name Acomplia, is sold in several foreign markets, primarily countries in the European Union. Sanofi-Aventis has been counting on the U.S. as its biggest market for what many analysts had forecast would provide annual sales of \$1 billion or more.*

*Zimulti has been plagued by regulatory setbacks in the U.S. The major issue is the concern that the drug increases the risk of suicidal thinking.*

*A Monday report by the staff of the FDA said a review of clinical trials showed 26% of patients taking the recommended dose of Zimulti had psychiatric side effects. By contrast, 14% of those receiving a placebo exhibited these side effects.* The report added that the drug achieved a statistically significant weight loss when compared with a placebo.

The panel's decision came after markets had closed. In regular trading, shares of Sanofi-Aventis were off \$1.31, or 3%, to \$42.64 as investors became nervous about Zimulti's fate. After hours, the stock fell another 43 cents, or 1%.

The Sanofi-Aventis drug has been before the FDA since April 2005. Since the application was filed, the agency had asked the company for more information about potential psychiatric side effects. [Emphasis added.]

30. On this news, the Company's securities declined \$1.31 per share, or 2.95 percent, to close on June 13, 2007 at \$43.07 per share, on unusually heavy trading volume. The following day, the Company's securities declined an additional \$1.74 per share, or over 4 percent, again on unusually heavy trading volume, for a two-day decline of \$3.05 per share, or over 6.87 percent.

31. On June 14, 2007, *Bloomberg* reported:

***Sanofi-Aventis SA shares had their biggest drop in three years, wiping out more than \$7 billion in market value, after a U.S. panel blocked the company's new weight-loss pill because it was linked to suicides.***

The stock fell 4.26 euros to 63 euros at the close of trading in Paris, the steepest decline since April 2004. The Paris-based company ***didn't get a single vote yesterday in favor of Zimulti from a Food and Drug Administration panel, which found that patients' weight loss didn't justify danger of the psychiatric or neurological dangers.***

***The world's third-largest drugmaker was counting on approval to lift the drug's sales to \$3 billion a year and revive growth as older best-sellers lose patent protection. The decision suggests Zimulti, sold as Acomplia in Europe, won't win the FDA's backing after three patients committed suicide in medical trials.***

"This is a major setback," said Laurent Vallee, who helps manage about \$5 billion in assets at Richelieu Finance in Paris. "Acomplia was slated to become a blockbuster. Sanofi needs a new growth driver."

***HSBC Securities analyst Kevin Scotcher cut his rating on Sanofi to "neutral" from "overweight" after the panel decision. Analysts at Merrill Lynch, ABN Amro and Societe Generale also reduced their recommendations while Morgan Stanley trimmed its price target and said it will review its rating. [Emphasis added.]***

#### **POST CLASS PERIOD DEVELOPMENTS**

32. On June 29, 2007, TheStreet.com published an article entitled "Sanofi Yanks Obesity Drug Application." The article, in relevant part, stated:

Sanofi-Aventis (SNY) has withdrawn its application for the obesity treatment Zimulti that was filed with U.S. regulators, but it said it will consider resubmitting the drug.

***The decision, announced Friday, is a major blow to the company's revenue projections. Still, the action isn't so surprising in light of a demonstrative rejection of the drug by a Food and Drug Administration advisory panel on June 13.***

Outside medical advisers to the FDA unanimously voted against the drug, saying Sanofi-Aventis hadn't provided enough safety information.

***The advisers said the drug's risks of psychiatric side effects were greater than its weight-loss benefits. They also concurred with an FDA staff report that trial data showed a heightened risk of suicidal thinking.***

***The staff review of the data showed 26% of patients taking Zimulti exhibited psychiatric side effects vs. 14% taking a placebo.*** [Emphasis added.]

### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

33. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Sanofi's securities between February 17, 2006 and June 13, 2007, inclusive (the "Class Period") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

34. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sanofi's securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sanofi or, its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

35. Plaintiff's claims are typical of the claims of the members of the Class as all

members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

36. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

37. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- (a) whether the federal securities laws were violated by defendants' acts as alleged herein;
- (b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Sanofi; and
- (c) to what extent the members of the Class have sustained damages and the proper measure of damages.

38. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **UNDISCLOSED ADVERSE FACTS**

39. The market for Sanofi's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements, and failures to

disclose, Sanofi's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Sanofi's securities relying upon the integrity of the market price of Sanofi's securities and market information relating to Sanofi, and have been damaged thereby.

40. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Sanofi's securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

41. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about Sanofi's financial well-being and prospects. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of Sanofi and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

#### **LOSS CAUSATION**

42. Defendants' wrongful conduct, as alleged herein, directly and proximately caused

the economic loss suffered by Plaintiff and the Class.

43. During the Class Period, Plaintiff and the Class purchased Sanofi's securities at artificially inflated prices and were damaged thereby. The price of Sanofi's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

#### **SCIENTER ALLEGATIONS**

44. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Sanofi, their control over, and/or receipt and/or modification of Sanofi's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Sanofi, participated in the fraudulent scheme alleged herein.

#### **Applicability of Presumption of Reliance: Fraud On The Market Doctrine**

45. At all relevant times, the market for Sanofi's securities was an efficient market for the following reasons, among others:

- (a) Sanofi's securities met the requirements for listing, and were listed and actively traded on the NYSE, a highly efficient and automated market;
- (b) As a regulated issuer, Sanofi filed periodic public reports with the SEC



and the NYSE;

- (c) Sanofi regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) Sanofi was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

46. As a result of the foregoing, the market for Sanofi's securities promptly digested current information regarding Sanofi from all publicly-available sources and reflected such information in the price of Sanofi's securities. Under these circumstances, all purchasers of Sanofi's securities during the Class Period suffered similar injury through their purchase of Sanofi's securities at artificially inflated prices and a presumption of reliance applies.

#### **NO SAFE HARBOR**

47. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the

extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Sanofi who knew that those statements were false when made.

**FIRST CLAIM**  
**Violation of Section 10(b) of**  
**The Exchange Act and Rule 10b-5**  
**Promulgated Thereunder Against All Defendants**

48. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

49. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Sanofi's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

50. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Sanofi's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

51. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Sanofi's financial well-being and prospects, as specified herein.

52. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Sanofi's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Sanofi and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Sanofi's securities during the Class Period.

53. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the

Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

54. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Sanofi's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's financial well-being and prospects throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

55. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Sanofi's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Sanofi's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by defendants, but not disclosed in public statements by defendants during the Class Period, Plaintiff and the other members of the Class acquired Sanofi's securities during the Class Period at artificially high prices and were damaged thereby.

56. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Sanofi was experiencing, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Sanofi securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

57. By virtue of the foregoing, defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

58. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

**SECOND CLAIM**  
**Violation of Section 20(a) of**  
**The Exchange Act Against the Individual Defendants**

59. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

60. The Individual Defendants acted as controlling persons of Sanofi within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various

statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

61. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

62. As set forth above, Sanofi and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses

- incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: December 31, 2007

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